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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.     | CONFIRMATION NO |
|--|-------------|----------------------|-------------------------|-----------------|
| 10/631,887   | 07/31/2003  | Wieslaw M. Cholody   | 689290-120              | 9810            |
| 7590 06/20/2005  |             |                      | EXAMINER                |                 |
| Alan J. Grant, Esq.  |             |                      | SHIAO, REI TSANG        |                 |
| c/o Carella, Byrne, Bain, Gilfillan, Cecchi<br>Stewart & Olstein |             |                      | ART UNIT                | PAPER NUMBER    |
| 6 Becker Farm Road<br>Roseland, NJ 07068                         |             |                      | 1626                    |                 |
|  |             |                      | DATE MAILED: 06/20/2005 |                 |

Please find below and/or attached an Office communication concerning this application or proceeding.

| •   |   | Application No. | Applicant(s)   |  |  |  |  |
|---|---|-----------------|----------------|--|--|--|--|
| Office Action Summary   |   | 10/631,887      | CHOLODY ET AL. |  |  |  |  |
|   |   | Examiner        | Art Unit       |  |  |  |  |
|   |   | Robert Shiao    | 1626           |  |  |  |  |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply  |   |                 |                |  |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). |   |                 |                |  |  |  |  |
| Status  |   |                 |                |  |  |  |  |
| 1)⊠   | 1) Responsive to communication(s) filed on <u>responses filed on 04/22, 2005</u> .                                |                 |                |  |  |  |  |
| 2a)□  | This action is <b>FINAL</b> . 2b)⊠ This action is non-final.  |                 |                |  |  |  |  |
|   | ) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is |                 |                |  |  |  |  |
|   | closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.                         |                 |                |  |  |  |  |
| Disposition of Claims   |   |                 |                |  |  |  |  |
| <ul> <li>4)  Claim(s) 1-41 is/are pending in the application.</li> <li>4a) Of the above claim(s) 20-39 is/are withdrawn from consideration.</li> <li>5)  Claim(s) is/are allowed.</li> <li>6)  Claim(s) 1-19,40 and 41 is/are rejected.</li> <li>7)  Claim(s) is/are objected to.</li> <li>8)  Claim(s) are subject to restriction and/or election requirement.</li> </ul>  |   |                 |                |  |  |  |  |
| Application Papers  |   |                 |                |  |  |  |  |
| 9) The specification is objected to by the Examiner.  |   |                 |                |  |  |  |  |
| 10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner.   |   |                 |                |  |  |  |  |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).   |   |                 |                |  |  |  |  |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.  |   |                 |                |  |  |  |  |
| Priority under 35 U.S.C. § 119  |   |                 |                |  |  |  |  |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  a) All b) Some * c) None of:  1. Certified copies of the priority documents have been received.  2. Certified copies of the priority documents have been received in Application No  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  * See the attached detailed Office action for a list of the certified copies not received.   |   |                 |                |  |  |  |  |
| Attachment(s)  1) Notice of References Cited (PTO-892)  4) Interview Summary (PTO-413)  |   |                 |                |  |  |  |  |
| 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date  6) Other:   |   |                 |                |  |  |  |  |

### **DETAILED ACTION**

1. Amendment including addition of claim 41 in the amendment filed on April 22, 2005, is acknowledged. No new matter is found. Claims 1-41 are pending in the application.

## Responses to Election/Restriction

2. Applicant's election with traverse without argument of Group II claims 1-19 and 40, in part, in the reply filed on April 22, 2005, is acknowledged.

#### Status of the Claims

3. Claims 1-41 are pending in the application. The scope of the invention of the elected subject matter is as follows:

Claims 1-19, and 40, in part, drawn to compounds/compositions of formula (I) or (II), wherein the variables  $R_1$ ,  $R_2$ ,  $R_3$ , and  $R_4$  independently do <u>not</u> represent heteroaryl or heterocyclalkyl, the variables  $R_1$ ,  $R_2$ ,  $R_3$ , and  $R_4$  independently are <u>not</u> substituted with heteroaryl or heterocycloalkyl; the heterocycloalkyl or heteroaryl of variables  $R_5$ , X or Y independently represents piperidine or pyridine thereof, or variables  $R_3$  and  $R_4$  are connected together to form a 4- or 7-membered heterocycle piperidine or pyridine thereof, the variable  $R_3$ ,  $R_4$ ,  $R_5$ , R

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withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention.

The requirement is still deemed proper and is therefore made FINAL.

## Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-19 and 40-41 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The formula (I) or (II) of claim 1 recites the variable  $R_5$  without limitation, is ambiguous and indefinite. Incorporation of limitation of " $R_5$ " into the claims would obviate the rejection, see page 16, lines 3-7.

#### Objection

5. Claims 1-19 and 40-41 are objected to as containing non-elected invention, i.e., heterocycle, heteroaryl, and morpholine, piperazine, or pyrrolidine moiety of claim 9 or 40, etc. It is suggested that applicants amend the claims to the scope of the elected subject matter as defined on the page 2 *supra*.

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**6**. Claim 40 is objected to as having typographic errors of not having a symbol "," between each named compound. Incorporation a symbol "," between each named compound would obviate the objection.

## Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Shiao whose telephone number is (571) 272-0707. The examiner can normally be reached on 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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TAOFIQ SOLOLA PRIMARY EXAMINER

Joseph K. McKane Supervisory Patent Examiner Art Unit 1626

Robert Shiao, Ph.D. Patent Examiner Art Unit 1626

June 09, 2005